

Dear Senators Vitter and Inhofe and Representatives Broun and Harris,

Thank you for your letter dated January 31, 2012, regarding the U.S. Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) Program, the Pathology Working Group (PWG) review of studies conducted by the Ramazzini Institute (RI), and the draft IRIS assessment for methanol.

In June 2010, the National Toxicology Program (NTP) issued a memo identifying discrepancies in the diagnoses of lymphomas and leukemias, as well as some of the reported solid tumors, identified by the RI for methanol. Because of the reported discrepancies, EPA undertook a thorough review of all IRIS assessments (draft and final) to determine if any of them substantially relied on RI cancer testing data. EPA identified four draft and two final IRIS assessments that substantially relied on findings from RI studies. The four draft assessments are: methanol (cancer), methyl tertiary-butyl ether (MTBE), ethyl tertiary-butyl ether (ETBE), and acrylonitrile. The two final assessments are: vinyl chloride and 1,1-dichloroethylene. In June 2010, EPA announced that it was putting the four draft assessments on hold pending further review.<sup>1</sup>

In April 2011, EPA announced it was collaborating with the National Institute of Environmental Health Sciences (NIEHS) to jointly sponsor an independent PWG review of selected studies to inform EPA's decisions on the use of RI data in IRIS assessments<sup>2</sup>. The PWG review was coordinated by NTP and performed by an independent contractor using NTP methods. While EPA jointly sponsored the PWG review, NTP is responsible for releasing the findings of the PWG.

Your letter also inquires about the draft IRIS assessment for methanol (noncancer), which was released for public comment and external peer review on April 18, 2011. This draft assessment does not rely quantitatively on RI data. In developing draft assessments, EPA conducts a thorough literature review and screens each study for its potential utility for deriving toxicity values. EPA has included in the draft methanol (noncancer) assessment one RI study related to the non-cancer health effects of methanol. This study was captured as part of the literature review and was included in the draft assessment for completeness. The study is not used or relied upon in the draft assessment in a substantive or quantitative fashion.

On July 22, 2011, the independent external peer review committee met to review EPA's draft IRIS assessment for methanol (noncancer). In October 2011, EPA released the comments from the public and external peer review panel. EPA takes seriously its commitment to rigorous, independent, expert peer review, and EPA is currently revising

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<sup>1</sup> EPA Press Release, "EPA Places Four IRIS Assessments on Hold Pending Review," June 15, 2010, available at: <http://yosemite.epa.gov/opa/admpress.nsf/03dd877d6f1726c28525735900404443/b64d44f06a56d5b285257742007c5002!OpenDocument>

<sup>2</sup> EPA Press Release, "EPA Announces Plan of Action to Address Four IRIS Assessments," April 11, 2011, available at: <http://yosemite.epa.gov/opa/admpress.nsf/48f0fa7dd51f9e9885257359003f5342/f88161843dbdd2a98525786f005b734b!OpenDocument>

the draft methanol (noncancer) assessment to address the public and peer review comments.

Again, thank you for your letter and your continued interest in the IRIS Program.

Sincerely,

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Assistant Administrator